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| APPLICATION NO.                                                     | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.       | CONFIRMATION NO.       |
|---------------------------------------------------------------------|-------------|----------------------|---------------------------|------------------------|
| 10/553,002                                                          | 10/11/2005  | Yoon-Seok Hur        | 5413YSH-1                 | 1279                   |
| 22442                                                               | 7590        | 10/02/2007           |                           |                        |
| SHERIDAN ROSS PC<br>1560 BROADWAY<br>SUITE 1200<br>DENVER, CO 80202 |             |                      | EXAMINER<br>NASH, BRIAN D |                        |
|                                                                     |             |                      | ART UNIT<br>3721          | PAPER NUMBER           |
|                                                                     |             |                      | MAIL DATE<br>10/02/2007   | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/553,002

Applicant(s)

HUR, YOON-SEOK

Examiner

Brian Nash

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 December 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Examiner's Comments***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/3/2007 has been entered. The pending claims remain 1-19.
2. Applicant's amendments have remedied the rejections made under 112, second paragraph with respect to claim 15; however, new issues of indefiniteness have been raised as discussed below.
3. The Examiner further notes US 5,271,543 to Grant et al, specifically figures 1, 6 and 7. Grant et al shows a transition section having a recessed portion wherein a side surface thereof is proximate to a head section cover such that a distance (a radial distance from a central longitudinal axis) from the axis to the recessed portion is less than a distance from the axis to a cylindrical body (70). However, Grant et al do not show the recessed portion to have a detachable cap coupled thereto as does Main et al.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 15, the terminology "a distance from the axis" is indefinite because it is not clear whether the distance is from a specific point on the axis or if the distance is a perpendicular distance, i.e. "a radial distance" from the axis. It is suggested that applicant amend the claims to define the distance to "a radial distance". The Examiner notes that since the claims have been interpreted in their broadest reasonable interpretation, the distance in question has been examined in lieu of the possibility it is from a

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specific point and therefore the reference to Main et al still anticipates the claimed invention. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-5, 8-9 and 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,533,661 to Main et al. Insofar as the invention is claimed, Main et al shows the same circular stapler.

With respect to claims 1 and 12, a detachable anvil (100), a head section (60) having a head section cover (61), a cylindrical body (70) coupled to the head section, a recessed portion (decreased diameter section formed on the cylindrical body under the head section cover – see Fig. 1) that is capable of receiving an inner portion of an intestine or a circumferential length of tubular tissue.

With respect to claim 2, the head section cover (61) has a circular plate shape (see Fig. 16).

With respect to claims 3-5, a cylindrical blade (69), a staple holder (68) having a plurality of slots (65), a push member (62) with a protruded portion (63), a support positioned under the push member and having a circular plate-shaped top (see Figs. 26-30 wherein Main et al shows an integral circular plate-shaped portion at the base of push member 62). The protruding portion (63) is formed thereon.

With respect to claim 8, the cylindrical body (70) has an arch shape (see Fig. 1).

With respect to claim 9, sections (64,72) are coupled and fixed to the recessed portion formed under the head section cover (61 – see Fig. 16).

With respect to claim 11, a trigger (86) provided at the lower end of the cylindrical body (70).

With respect to claims 13 and 14, the circular surgical stapler of Main et al is certainly capable of performing both end to end tubular anastomosis and end to side anastomosis (see column 1, lines 45-55).

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***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 6-7, 10 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,533,661 to Main et al. As discussed above, Main et al shows the invention substantially as claimed.

With respect to claim 6, Main et al disclose the anvil shaft to be made of stainless steel, but do not explicitly disclose the other portions of the stapler, specifically the circular plate-shaped top of the support member, to be made of steel. It is well known in the art to use stainless steel when making surgical staplers and would have been obvious to one having ordinary skill in the art at the time the invention was made to configure/modify the circular head of the support member, which is integral to the push member, out of stainless steel, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

With respect to claim 7, Main et al disclose the claimed invention except for the head section cover to be set to a length of 15-18 mm. It would have been an obvious matter of design choice to configure/modify the head section cover (61) since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art.

With respect to claim 10, Main et al disclose the claimed invention except for the shaft passing through the head section be set to a diameter of 1.0-1.5 mm. It would have been an obvious matter of design choice to configure/modify the shaft passing through the head section (104) since such a

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modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art.

With respect to claims 15 and 17, Main et al shows a detachable anvil (100), a head section (60) having a head section cover (61), a cylindrical body (70) coupled to the head section, a recessed portion (decreased diameter section formed on the cylindrical body under the head section cover – see Fig. 1) that is capable of receiving an inner portion of an intestine or a circumferential length of tubular tissue; and a cylindrical blade (69), a staple holder (68) having a plurality of slots (65), a push member (62) with a protruded portion (63), a support positioned under the push member and having a circular plate-shaped top (see Figs. 26-30 wherein Main et al shows an integral circular plate-shaped portion at the base of push member 62), the protruding portion (63) is formed thereon. With respect to length of the head section cover being less than about 18mm (see rejection above under 35 U.S.C. 112, second paragraph) it would have been an obvious matter of design choice to configure/modify the head section cover (61) since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art.

With respect to claim 16, sections (64,72) are coupled and fixed to the recessed portion formed under the head section cover (61 – see Fig. 16).

With respect to claims 18 and 19, the circular surgical stapler of Main et al is certainly capable of performing both end to end tubular anastomosis and end to side anastomosis (see column 1, lines 45-55).

### ***Conclusion***

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Refer to attachment (PTO-892) for notice of references cited and recommended for consideration based on their disclosure of limitations of the claimed invention.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Nash whose telephone number is 571-272-4465. The examiner can normally be reached on Monday – Thursday from 8 a.m. to 6 p.m.

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12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi I. Rada can be reached at 571-272-4467. The official fax number for this Group is: 571-273-8300

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Brian D. Nash/  
Primary Examiner, Art Unit 3721

9/15/2007